Remarks

Reconsideration of the above-identified application in view of the present amendment is respectfully requested. By the present amendment, claim 22 has been amended and claims 36-41 are cancelled. Claims 1-5, 7-8, 10-12, 15 and 18-23 are pending in the application.

Preliminary Matters

In the current Office Action, the Examiner asserts that although the Applicants have amended the claims to include previously allowable subject matter, the Examiner has discovered a new reference to Singhal (U.S. Patent Publication No. 2005/0004637) which revokes allowability of those claims. Applicants respectfully submit that Singhal is not a new reference, and was used to reject claims 1, 7, 8, 12, 13, 22, and 25-28 in the Office Action of September 26, 2006 under 35 U.S.C. §102(e). In response, Applicants cancelled claims 13, 14, and 24-28 and amended claims 1, 12, and 22 to incorporate allowable subject matter to overcome the rejection to Singhal in its entirety. Attention is drawn to MPEP §706.04, in which the Examiner is reminded that:

> A claim noted as allowable shall thereafter be rejected only after the proposed rejection has been submitted to the primary examiner for consideration of all the facts and approval of the proposed action [and that]
>
> [f]ull faith and credit should be given to the search and action of a previous examiner unless there is a clear error in the previous action or knowledge of other prior art. In general, an examiner should not take an entirely new approach or attempt to reorient the point of view of a previous examiner.

In issuing such a rejection, the Examiner should point out in his or her Office Action that the claim now being rejected was previously allowed using Form paragraph 7.50, entitled "Claims Previously Allowed, Now Rejected, *New* Art" (emphasis added) (MPEP §706.04). As noted, Singhal is not new art. Therefore, it is believed that the rejections to Singhal under 35 U.S.C. §102(e) and §103(a) are erroneous. It is therefore respectfully submitted that the rejections to Singhal be withdrawn. Notwithstanding Applicants' remarks regarding the applicability of Singhal to the present Office Action, Applicants address the rejections of the claims on the merits.

Claim Rejections under 35 U.S.C. §112

The Examiner rejected pending claims 1, 12 and 22 under 35 U.S.C. §112, first paragraph, as being non-enabling. In particular, the Examiner asserts there is insufficient antecedent basis for the limitation of "distinct sections" in claim 1 and "different sections" in claims 12 and that the Applicants do not disclose in the specification what makes the sections of the lead "different" or "distinct" sections. That rejection is respectfully traversed.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988)(MPEP §2164.01). Any part of the specification can support an enabling disclosure, even a background section that discusses, or even disparages, the subject matter disclosed therein. *Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 77 USPQ2d 1041

(Fed. Cir. 2005)(emphasis added). Therefore, the drawings can be supportive of an enabling disclosure. As shown in Figs. 5B-5F, for example, the lead retainers clearly retain different or distinct portions of the lead in that each portion of the lead retained in each separate groove is discernable or linearly displaced from the next. Therefore, recitation of "discrete" or "different" in claims 1, 12 and 22 is enabled by the drawings in the specification. Accordingly, it is respectfully submitted that the rejection to claims 1, 12 and 22 be withdrawn.

The Examiner rejected pending claims 1 and 22 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter Applicants regard as the invention. In particular, the Examiner asserts that claims 1 and 22 do not positively recite a lead. However, a lead is recited in the preamble of each of the rejected claims, and then recited within the body of each claim. In practice,

> [a] preamble has been denied the effect of a limitation where the claim or count was drawn to a structure and the portion of the claim following the preamble was a self-contained description of the structure not depending for completeness upon the introductory clause. . . On the other hand. . . where the preamble to the claim or count was expressly or by necessary implication given the effect of a limitation, the introductory phrase was deemed essential to point out the invention defined by the claim or count. . . [T]he preamble was considered necessary to give life, meaning and vitality to the claims.

Kropa v. Robie, 187 F.2d 150 at 152, 88 USPQ 478 (CCPA 1951). In this case, the recitation of the lead in the preamble is necessary to give life to the inferential claim of the lead in the body of the claim, and thus the lead can be read into the claim as a

limitation. Therefore, it is respectfully submitted that the rejection to claims 1, 12 and 22 be withdrawn.

Claim Rejections under 35 U.S.C. §102

The Examiner rejected claims 12, 15, and 20-23 under 35 U.S.C. §102(e) as being fully anticipated by U.S. Patent Appln. No. 2005/0004637 to Singhal, et al. (hereafter "Singhal"). It is respectfully submitted that claim 12 is not fully anticipated by Singhal, and is therefore allowable.

Claim 12 recites a flange extends from the sleeve and that the flange has means for at least partially retaining a plurality of different sections of the excess portion of the lead, the retaining means including a plurality of tabs extending from an outside surface of the flange, the tabs configured to form a groove between adjacent tabs to thereby form a plurality of grooves to retain the plurality of different sections of the excess portion of the lead.

Singhal appears to teach a burr hole cap 140 comprising ring member 142 and a cover member 144 (paragraph 0063 and Fig. 8). The ring member 142 further includes a lead management system, being a groove 146, which receives lead 148. The implanting surgeon can coil lead 148 inside groove 146, and draw the lead through exit 150 (paragraph 0064 and Fig. 8). The Examiner asserts that ring member 142 is a flange, and that exit 150 is a groove defined by a plurality of tabs designated by "A" (see Office Action page 4). The Examiner further asserts that the inside groove 146 and the cut out in the core of the burr hole cap constitute a plurality of grooves (*Id.*). However, Singhal does not teach that the flange has a plurality of grooves, as recited in claim 12. The only groove in the flange 142 the

Examiner designates is the exit 150. Since Singhal does not teach or suggest a flange having retaining means constituting a plurality of grooves, as recited in claim 12, it is respectfully submitted that claim 12 is not fully anticipated by Singhal, and is therefore allowable.

Claim 15 recites that the outside surface of the burr hole ring including a spiral groove that extends from the aperture to at least one outlet periphery of the outside surface of the burr ring, the spiral groove dimensioned such that the excess portion of the lead can be stored in at least one loop in the spiral groove.

Singhal appears to teach that burr cap 140 includes ring member 142 having a groove 146 for receiving lead 148 (paragraphs 0063-0064 and Fig. 8). The Examiner asserts that groove 146 is spiral because it extends from the aperture to at least one periphery of the outside surface of the burr ring (see Office Action at page 4). However, this limitation in claim 15 does not define the groove itself, it defines the path through which the groove must extend. That being said, merely because groove 146 extends from the aperture in the middle of burr hole cap 140 to the exit 150 does not make the groove spiral. In fact, groove 146 in Fig. 8 is ring-shaped, as opposed to the spiral groove of the present invention (see Figs. 8A-8C), even though both grooves extend from an aperture in the burr ring to at least one outlet periphery of the outside surface of the burr ring. Since Singhal does not teach or suggest that the outside surface of the burr hole ring includes a spiral groove, it is respectfully submitted that claim 15 is not fully anticipated by Singhal, and is therefore allowable.

Claims 20-21 depend from claim 15 and are allowable for at least the same reasons claim 15 is allowable, and for the specific limitations recited therein.

As amended, claim 22 recites that at least one lead retainer extends from the ring, the at least one lead retainer comprising a plurality of spaced apart grooves to releasably retain the plurality of difference sections of the lead.

Singhal appears to teach a burr hole cap 140 comprising ring member 142 and a cover member 144 (paragraph 0063 and Fig. 8). The ring member 142 further includes a lead management system, being a groove 146, which receives lead 148. The implanting surgeon can coil lead 148 inside groove 146, and draw the lead through exit 150 (paragraph 0064 and Fig. 8). The Examiner asserts that ring member 142 is a flange, and that exit 150 is a groove defined by a plurality of tabs designated by "A" (see Office Action page 4). The Examiner further asserts that the inside groove 146 and the cut out in the core of the burr hole cap constitute a plurality of grooves (*Id.*). The plurality of grooves asserted by the Examiner are not spaced apart from one another, as recited in amended claim 22. Groove 146, exit 150, and the inner core of the burr hole ring are interconnected with no space separating any one groove from another. The lead extends from the inner core of the burr hole ring, directly into groove 146, and finally directly into exit 150. Since Singhal does not teach or suggest a plurality of spaced apart grooves, as recited in amended claim 22, it is respectfully submitted that claim 22, as amended, is not fully anticipated by Singhal, and is therefore allowable.

Claim 23 recites a plurality of lead retainers disposed at spaced apart locations with respect to the ring. As noted with respect to claim 22, Singhal does

not teach a plurality of retaining members spaced apart from one another. Any means utilized to retain lead 148, including groove 146, the inner core of the burr hole ring 140, and exit 150, are interconnected. Since Singhal does not teach or suggest a plurality of retaining members disposed at spaced apart locations, as recited in claim 23, it is respectfully submitted that claim 23 is not fully anticipated by Singhal, and is therefore allowable.

Claim Rejections under 35 U.S.C. §103

The Examiner rejected claims 1-5, 7-8, and 10-11 under 35 U.S.C. §103(a) as being unpatentable over Singhal. It is respectfully submitted that claim 1 patentably defines over Singhal, and is therefore allowable.

Claim 1 recites that the width of each groove is less than the outside diameter of the lead, wherein the width of each groove is configured to accept the lead by increasing the width of the groove a distance at least as great as the outside diameter of the lead when a force is being applied to insert the lead into one of the grooves.

Singhal appears to teach that the lead 148 is drawn through the inner core of the ring 140 (a groove as designated by the Examiner), coiled around groove 146, and drawn through exit 150 (paragraph 0063 and Fig. 1). It would not have been obvious to one skilled in the art to modify all the grooves the Examiner designates, namely, groove 146, the inner core of the ring 140, and the exit port 150, to have widths less than that of the lead 148. Drawing the lead 148 from inside the patient through the inner core of the ring 140 would be exceedingly difficult if the width of the core was less than the diameter of the lead 148. Furthermore, due to its location in

ring 140, the groove would be incapable of increasing in width to accommodate the lead when a force is applied to insert the lead, as recited by claim 1.

It would also not be obvious to make the width of groove 146 less than the diameter of the lead 148. Burr rings are designed to be low profile such that they can be inconspicuously retained under the scalp of the patient without discomfort. If the width of groove 146 was smaller than diameter of the lead 148, the lead 148 would have to be stacked on top of itself with each successive coil around the ring, which would increase the overall height of the ring 140 – an unwanted configuration. With groove 146 currently being much wider than the diameter of the lead 148 (see Fig. 8), the coiling of the lead 148 maintains a lower profile within the groove 146, which subsequently allows the ring 140 to remain low profile. Since it would not have been obvious to modify all the grooves in Singhal such that each groove has a width less than the outside diameter of the lead, whereby each groove is configured to accept the lead by increasing in width, as recited in claim 1, it is respectfully submitted that claim 1 patentably defines over Singhal, and is therefore allowable.

Claim 2 recites that the lead retainer is connected to the burr ring by an integral living hinge. Singhal does not teach a hinge of any kind connecting the burr ring 142 to a lead retainer. The lead retainers the Examiner points out, including groove 146, exit port 150, and the inner core of the ring 140, are all integrally formed with the burr ring 142. Thus, it would not have been obvious to include hinges of any kind in the Singhal device. Since Singhal does not teach or suggest a living hinge connecting the lead retainer to the burr ring, and it would not have been obvious to

include such a hinge, as recited in claim 2, it is respectfully submitted that claim 2 is allowable.

Claim 3 recites that the living hinge permits relative movement between the lead retainer and the burr hole ring between expanded and collapsed positions. As noted with respect to claim 2, Singhal does not teach such a hinge, nor would it have been obvious to include such a hinge in the Singhal device. Since Singhal does not teach or suggest a living hinge that permits relative movement between the lead retainer and the burr hole ring between expanded and collapsed positions, and it would not have been obvious to include such a hinge, as recited in claim 3, it is respectfully submitted that claim 3 is allowable.

Claim 4 recites that the lead retainer is pivotally connected to the burr ring. Singhal does not teach a pivotal connection between the burr ring and any of the lead retaining means, namely, groove 146, exit 150, or the inner core of the ring because these lead retainers are integrally formed with burr ring 142. Thus, it would not have been obvious to include hinges of any kind in the Singhal device. Since Singhal does not teach or suggest that the lead retainer is pivotally connected to the burr ring, and it would not have been obvious to include such a connection, as recited in claim 4, it is respectfully submitted that claim 4 is allowable.

Claim 5 recites a pivot hinge to selectively enable the lead retainer to move between expanded and collapsed positions. Singhal does not teach that the lead retainers, namely, groove 146, exit 150, and the inner core of the ring 140, move from expanded to collapsed conditions. These retainers are integrally formed with burr ring 142 and thus do not move at all. Thus, it would not have been obvious to

include hinges of any kind in the Singhal device. Since Singhal does not teach or suggest a pivot hinge that selectively enables the lead retainer to move between expanded and collapsed positions, and it would not have been obvious to include such a connection, as recited in claim 5, it is respectfully submitted that claim 5 is allowable.

Claims 7-8 and 10-11 depend from claim 1 and are allowable for at least the same reasons claim 1 is allowable, and for the specific limitations recited therein.

The Examiner rejected claims 1-5, 7-8, and 10-11 under 35 U.S.C. §103(a) as being unpatentable over PCT International Appln. No. PCT/GB03/00539 to Mogg (hereafter "Mogg"). It is respectfully submitted that claim 1 patentably defines over Mogg, and is therefore allowable.

Claim 1 recites a burr hole ring configured to be secured to a skull of the patient and a lead retainer comprising a plurality of grooves, each groove having a width that is less than an outside diameter of the lead, the width of each groove configured to accept the lead by increasing the width of the groove a distance at least as great as the outside diameter of the lead when a force is applied to insert the lead into one of the grooves.

Mogg appears to teach that a catheter 2 is retained by clamping means 3 and body 5. The body 5 comprises location means in the form of a passageway which comprises first portion 11, second portion 12, and third portion 13 (page 5, lines 21-25 and Fig. 1). Third portion 13 comprises horizontal channel 15 and inclined channel 14, which itself comprises three equi-spaced ribs 16 which extend substantially perpendicular to the longitudinal axis of the channel 14. First

portion 11, second portion 12, and channel 14 are formed in bridge portion 24 (page 6, lines 9-11 and Figs. 1-2). Horizontal channel 15 is provided by a recess formed in interface surface 26, is aligned with inclined channel 14 (page 7, lines 6-9 and Figs. 1-2), and is flanked by the two inclined surfaces 32 (best seen in Fig. 1) of bridge portion 24 (page 6, lines 14-16). Once the catheter 2 is fed through first portion 11, the appropriate portion of the catheter 2 is then urged into the channel portions 14 and 15 which are dimensioned to provide a close fitting pathway for the catheter (page 9, line 18 – page 10, line 4; Fig. 1). In the clamping position, a portion 115 of the underside of the clamping means 3 engages with the portion of the catheter 2 within channel portions 14 and 15 to urge the catheter into said channel portions. The ribs 16 act to substantially restrict movement of the catheter in a direction which is substantially parallel to the longitudinal axis of the channel portions (page 10, lines 17-24 and Fig. 1).

Mogg does not teach or suggest that channel portions 14 and 15 are configured to accept the lead by increasing the width of the groove a distance at least as great as the outside diameter of the lead when a force is being applied to insert the lead into one of the grooves. Mogg also does not teach or suggest that inclined surfaces 32 that flank, and thereby define, channel 15 are either spaced apart a distance less than the diameter of catheter 2 or configured to increase in width to accept catheter 2. Nor does Mogg teach or suggest that bridge portion 24, which helps define channel 14, is capable of such movement to accommodate catheter 2.

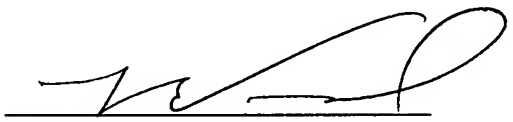
Furthermore, it would not obvious to have modified the clamping system as taught by Mogg to a lead for placement in a burr hole. The device in Mogg is secured to the patient's skin by removing release paper on the underside of foam pad 7, revealing adhesive that contacts the patient's skin to hold the clamp in position (page 9, lines 22-25). Mere adhesion of the device to the burr hole of a skull would be an insufficient securing means, as it is very important for the device to remain in one position relative to the patient's brain when implantable medical devices are utilized, such as a lead implanted within the patient's brain. That is why burr hole rings are frequently adapted to be placed at least partially within the burr hole to ensure the device doesn't move. The device in Mogg would require more than ordinary skill to become capable of being secured to a burr hole. Since Mogg does not teach or suggest the subject matter of claim 1, and it would not have been obvious to adapt Mogg to include the subject matter of claim 1, it is respectfully submitted that claim 1 patentably defines over Mogg, and is allowable.

Claims 4-5, 7-8, and 10-11 depend from claim 1 and are allowable for the same reasons claim 1 is allowable, and for the specific limitations recited therein.

In view of the foregoing, it is submitted that the application is in condition for allowance and allowance is respectfully requested.

Please charge any deficiency or credit any overpayment in the fees for this amendment to our Deposit Account No. 20-0090.

Respectfully submitted,



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